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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,330

06/26/2003

Armand Malnoe

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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT

PAPER NUMBER

1661

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/607,330

Applicant(s)

MALNOE ET AL.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8,10,11,14,16,18 and 23-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,10,11,14,16,18,63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment of January 30, 2007 is hereby acknowledged.

Applicant elected Group I and chicory in the Restriction Requirement dated February 8, 2005.

Claims Pending

Claims 1, 3-4, 6, 8, 10-11, 14, 16, 18 and 23-64 are pending. Applicant has cancelled claims 2, 5, 7, 9, 12-13, 15, 17, 19-22. Claims 23-62 have been withdrawn from consideration. Claims 1, 3-4, 6, 8, 10-11, 14, 16, 18 and 63-64 will be examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Written Description

Claim 1 is drawn to plant material. In analyzing whether the written description requirement is met for genus claims, it is determined whether a representative number have been described. In this case, the one disclosed embodiment (i.e. chicory) is not representative of the enormous number of plant material claimed. The specification only provides plants of chicory. Therefore, Applicant is not in possession of the claimed plant material at the time this application was filed and lacks an adequate written description.

Claim 4 is drawn to the family *Asteracea* and the claimed chicory plant. In analyzing whether the written description requirement is met for genus claims, it is determined whether a representative number have been described. In this case, the one

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disclosed embodiment is not representative of the enormous number of plants claimed. *Asteracea* contains thousands of different plants species. The specification only provides plants of chicory. Therefore, Applicant is not in possession of the claimed plant at the time this application was filed and lacks an adequate written description.

In response to **Applicant argument** that the specification discloses several plant species of *Asteracea* that contain phytochemical agents and several plant materials outside the family of *Asteracea* that also contain phytochemical agents. The argument is not persuasive because of the number of plant materials is not a representative number. In addition, the common function (i.e. phytochemical agents and enzymatic and transcriptional activity to inhibit inflammation) is so broad it is impossible to describe which plant material Applicant is describing. There are hundreds of different plant materials that can function as the claimed invention. Take for example, willow (i.e. family Salicaceae), vervain (i.e. family Verbenaceae), pineapple (i.e. family Bromeliaceae) and raspberry (i.e. family Rosaceae) are known to contain phytochemical agents to inhibit inflammation.

Therefore, the rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, and 10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Anantharaman *et al.* (US 5,952,033) for reasons set forth in the previous Office action which are restated below. Applicant's arguments filed January 30, 2007 have been fully considered but they are not persuasive.

Anantharaman *et al.* (US 5,952,033) expressly teaches using a plant material extract (i.e. chicory) in a composition, which includes a starch source, a protein source

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and a fat source. The amount of chicory extract used is about 1% to about 5% by weight (col. 3, lines 23-66; col. 6, lines 42-43). Anantharaman also teaches the feed is fed into an extruder (col. lines 8-9). It is noted that in the Applicant's specification on page 3, line 22, that the term "thermally processed" also can mean "extruded." Therefore, Anantharaman meets the limitations of claim 1 as the composition comprises a thermally processed plant material containing chicory extract and a starch source, protein source and fat source where the amounts are from 1% to 5% and thus anticipates the claimed invention.

Applicant is requested to note that it is regarded that "intended use" of a composition will not further limit claims drawn to a composition. See, e.g., *Ex Parte Masham*, 2 USPQ2d 1647 (1987) and *In Re Hack* 114, USPQ 161. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that Anantharaman fails to disclose or suggest the thermal process of the claimed invention such as Anantharaman discloses treating a plant material via a process where the material must be gelantized in order to remove or destroy the sesquiterpene compounds present in the inulin-containing plant material which is in contrast with the Applicant's invention. This is not found persuasive because sesquiterpene compounds are present as Anantharaman discloses that "between 380 to 680 ppm bound sesquiterpene lactones." (emphasis added) (col. 7, lines 33-34). The "ppm" (i.e. parts per million) denotes that there are some sesquiterpene lactones present in the extract.

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Applicant argues that Anantharaman fails to disclose or suggest a thermally processed plant material that includes one or more phytochemical agents capable of inhibiting at least one of enzymatic and transcriptional activity to inhibit inflammation in a mammal. This is not found persuasive, as discussed in the above rejection, the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since Anantharaman discloses that sesquiterpene lactones are present in the extract (see col. 7, lines 33-34), therefore the composition would be the same.

Therefore, the rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6, 8, 10-11, 14, 16, 18 and 63-64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hermand (US 6,645,534 B2) in view of Anantharaman *et al.* (US 5,952,033) in view of Hwang *et al.* (US 5,905,089). Applicant's arguments filed January 30, 2007 have been fully considered but they are not persuasive.

Hermand (US 6,645,534 B2) discloses that chicory is capable of pharmacological properties such as anti-inflammatory efficacies. In addition, Hermand teaches extracting chicory by hot extraction method (i.e. thermal) (col. 1, lines 21-27; col. 2, lines 38-41). Also, Hermand discloses that the plant material (i.e. chicory extract) comprises an amount of about 4.5% by weight (col. 6, lines 19-21).

Hermand does not teach wherein the composition further comprises a starch source, a protein source and a fat source.

Anantharaman *et al.* (US 5,952,033) disclose using a plant material extract (i.e. chicory) in a composition, which includes a starch source, a protein source and a fat

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source. The amount of chicory extract used is about 1% to about 5% by weight (col. 3, lines 23-66; col. 6, lines 42-43). Anantharaman also discloses the feed is fed into an extruder (i.e. thermally processed) (col. lines 8-9).

Hwang *et al.* (US 5,905,089) disclose that sesquiterpene lactones, obtained from plant material, possess an α -methylene γ -lactone group which suppresses the expression of the inducible cyclooxygenase-2. In addition, Hwang discloses sesquiterpene lactones are useful in suppressing early proinflammatory cytokines and proteins, and in ameliorating severe inflammatory disorders (col. 4, lines 59-67; col. 5, lines 1-2, 45-50; col. 6, lines 15-18, 28)

One of ordinary skill in the art would have been motivated to use chicory extract to obtain sesquiterpene lactones along with a starch, a protein and a fat in a composition because of the known anti-inflammatory properties that chicory contains and the addition of starch, protein and fat would make the composition more palatable for ease of administration. It was clear from the Hermand reference that that chicory has anti-inflammatory properties and can be thermally extracted. It was further clear from the Anantharaman reference that a plant material extract (i.e. chicory) is used in a composition, which includes a starch source, a protein source and a fat source with the amount of chicory extract about 1% to about 5% by weight. It was further clear from the Hwang reference that sesquiterpene lactones, obtained from plant material, possess an α -methylene γ -lactone group which suppresses the expression of the inducible cyclooxygenase-2 and sesquiterpene lactones are useful in suppressing early proinflammatory cytokines and proteins, and in ameliorating severe inflammatory disorders. Although none of the references disclose the specific active fragment of α -methylene- γ -butyrolactone, it would be inherent to the composition. Therefore, one of ordinary skill in the art would have had a reasonable expectation to use chicory in a composition because of the anti-inflammatory properties it contains.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Applicant's arguments concerning the above art rejection have been fully considered but are not deemed to be persuasive.

Applicant argues that there is no suggestion or motivation to combine Hermand and Anantharaman because the cited references are directed to unrelated inventions. This is not found persuasive because the Hermand discloses that chicory has anti-inflammatory efficacies and discloses chicory can also be extracted by the hot extraction method and Anantharaman discloses that composition contains chicory extract along with a starch source, a fat source and a protein source.

Applicant argues that one of ordinary skill in the art would not be motivated by to add a starch source, a protein source or a fat source from a food product to a toothpaste or mouthwash in order to make the toothpaste or mouthwash more palatable for ease of administration because toothpaste and mouthwash are not food and are not intended to be ingested. This is not found persuasive because as evidenced by Cocherell (US 5,004,596), which discloses a toothpaste composition, contains a starch source (i.e. cornstarch) and a fat source (i.e. cottonseed oil, sunflower oil, soybean oil, corn oil, coconut oil, rapeseed oil) (col. 1, lines 36-48; col. 4, lines 58-62). Thus, it was known in the art that a starch source and a fat source have been known to be in toothpaste compositions.

Applicant argues that Hermand fails to disclose a plant material that is thermally processed. Applicant states that the term "thermally processed" requires heating the plant raw material above standard temperature (e.g. 25° or 298 kelvins) in a dedicated device. Hermand discloses that that chicory can be roasted whose final temperature does not exceed 170°C and can be in the form of grains, ground grains, powder, liquid or paste (see col. 2, lines 15-20). Additionally, Hermand discloses that the extract obtained by the process has all the known properties of the chicory extract obtained by hot extraction (col. 2, lines 38-40.) Therefore, Hermand discloses that chicory extract is known to be obtained by hot extraction.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


CHRISTOPHER R. TATE
PRIMARY EXAMINER